DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration
Los Angeles District

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Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 13, 2004 **WL-27-04**

Brett Milligan, President
MacKnight Smoked Foods, Inc.,
10150 Highland Manor Drive
Tampa, FL 33610

Dear Mr. Milligan:

We inspected your seafood processing facility, located at 1030 B Cindy Lane, Carpinteria, CA, on November 5-7, 2003. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a) (4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a) (4). Accordingly your cold-smoked fishery products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP Regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cold-smoked salmon lists time and temperature critical limits, [redacted] at the Curing critical control point that are not adequate to control pathogen growth.

   Allowing refrigerated product to remain above refrigerated temperatures (i.e. 40°F) is not suitable in a HACCP plan, especially for a product that is ready-to-eat and is not

subjected to a thermal process designed to eliminate harmful bacteria, such as is the case with your cold-smoked salmon. Furthermore, your critical limits at this step do not indicate whether this temperature critical limit is cumulative over the entire curing cycle or per each out of temperature episode. The cumulative amount of time that in-process product is held at temperatures favorable to bacteria growth should be measured, in order to keep it to a minimum.

Because your salmon during the curing step is being dry-cured for over four (4) hours, the temperature during the curing step should not exceed 40°F at any time. FDA recommends that this temperature should be continuously recorded and periodically monitored manually during the curing step to ensure the recorder is functioning properly. It would also be advisable to have a high temperature alarm to alert you to a mechanical failure in the system.

Your lack of adequate critical limits for time / temperature parameters to control pathogen growth during the Curing critical control point was also brought to your attention during a previous inspection of your Carpinteria facility.

2. You must implement the monitoring and record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not monitor critical limits or record monitoring observations at the following critical control points to control *Clostridium botulinum* listed in your HACCP plan for cold smoked salmon:

   a) Maximum dry curing time is not being recorded; however the curing critical control point of your HACCP plan for cold-smoked salmon states [redacted]

   b) The curing critical control point also requires [redacted] a minimum amount of salt [redacted] but the amount of salt being applied is not being monitored and recorded. Your HACCP plan for cold-smoked salmon states that the [redacted] weight of salt used per fish batch will be measured [redacted]

   c) The weight of fish used per batch is not being monitored or recorded, although your HACCP plan for cold-smoked salmon at the curing critical control point states that the [redacted] weight of fish used per fish batch will be measured [redacted]

   d) Water Phase Salt testing for [redacted] is not being performed [redacted] as stated in your firm's HACCP plan for cold-smoked fish at the Drying Room / Unpacked Cold Storage critical control point .

Monitoring deficiencies regarding your failure to record salt and fish weights and total curing time during the Curing critical control point have been cited before in a previous inspection.

3. You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures that no product enters commerce that is either injurious to health or is otherwise

adulterated as a result of the deviation and that the cause of the deviation is corrected. However, your firm did not take a corrective action to control pathogen growth when your process for cold-smoked salmon deviated from your critical limit [redacted] at the Drying Room / Unpacked Cold Storage and Finished Product Cold Storage critical control points.

Failure to take a corrective action when a critical limit was not met was previously cited at this facility during the August 2001 inspection.

4. Since you chose to include corrective actions in your HACCP plan for cold-smoked salmon, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Section 123.7(b) requires that you ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. However, your corrective action plan for cold-smoked salmon at the Drying Room / Unpacked Cold Storage critical control point is not appropriate because it does not address the products affected by the deviation. Instead, [redacted] Thus, it would permit adulterated products to enter commerce. Moreover, the cause of the deviation must also be corrected to comply with 123.7. In this case, you should not have low water phase salt results if your curing procedures (critical limits) were followed properly. Your investigation into the deviation, as well as your conclusion which includes the disposition of the affected lot of cold-smoked salmon, must be documented. All corrective actions taken must be fully documented in records that are subject to verification under 21 CFR 123.8(a)(3)(ii) and the recordkeeping requirements of 21 CFR 123.9.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the required areas of sanitation with sufficient frequency to ensure the protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensates, and other chemical, physical, and biological contaminants, as evidenced by:

   a) Unlabeled spray bottles of hand sanitizer (71% Ethanol solution and Quaternary Ammonium solution) in the processing room and adjacent areas.
   b) Mold was observed on the outer wall at the freezer near the smoker.
   c) Boxes of smoked salmon were stored directly on the floor of the freezer and frozen pooled condensation was observed on and around those boxes.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as HACCP plans, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

We received a response to the FDA-483 dated 11/07/03 via fax from [redacted] on 11/13/03 (enclosed). While we find that many of the specific items in the FDA-483 seem to be addressed, we will not be able to confirm these corrections until a reinspection occurs. In the meantime, to address the items in this letter, please include any revised forms as indicated in [redacted] fax, including HACCP plans, with your future response(s). We do not believe that the response to item number three is adequate, in that this response does not address the requirement to document the corrective action when a deviation from a critical limit occurs, or the disposition of the affected lots of products specifically described in the FDA-483 item. In addition, please note a general comment that a maximum time limit for the Curing step may not be necessary as a critical limit if your temperature limit is lowered to a temperature that will not allow rapid bacteria growth (e.g. 40°F or lower).

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

If you have any specific questions regarding this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 608-4409. Your written reply should be addressed to:

Director, Compliance Branch
U. S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2445

Sincerely,

Alonza E. Cruse
District Director

Enclosure

cc: [redacted] Operations Manager
990 Cindy Lane, Suite A
Carpinteria, CA 93013-2906